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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,507	06/22/2001	Norio Miura	KIP 002	5780

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EXAMINER

CHIN, CHRISTOPHER L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/887,507

Applicant(s)

MIURA

Examiner

Christopher L. Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague. The fourth step is vague because the prepared sample contains more of the same antibody that has been coupled to the protein antigen on the resonance material in the third step. The function of the antibody for measuring the medical substance is not clearly defined since some of the antibody is coupled to the fixed protein conjugate while other antibodies are in solution according to steps three and four.

Applicant's amendments and arguments did not address this part of the previous rejection to claim 1 and is thus being maintained.

### ***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 6-13 and 15-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-23 and 26-27 of copending Application No. 08/985,007. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending '007 claims an apparatus with essentially the same limitations as the instantly claimed apparatus.

Copending '007 claims an apparatus for measuring a medical substance in a sample comprising:

a resonance phenomenon generating section having a resonance material;  
a detecting means for detecting a change of an incident light which is made incident upon said resonance material to generate said resonance phenomenon or a change of a reflected light thereof; and

wherein the medical substance to be measured is fixed to said resonance material as an antigen.

Copending '007 differs from the instant invention in not defining the conjugated protein antigen fixed to the resonance material as being almost identical to that of the medical substance that is to be detected.

However, it would have been obvious to one of ordinary skill in the art that the antigen in the apparatus of copending '007 is almost identical to the medical substance

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that is to be detected because copending '007 refers to the antigen as the medical substance which is the same medical substance that is to be detected.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Partin et al (US Patent 5,082,630) for the reasons of record in the previous office action.

In response to this rejection, Applicants argue that claim 6 requires a conjugated protein antigen with a reaction site which is essentially identical to that of the medical substance that is to be detected and which is fixed to the resonance material which is different from the structure of Partin et al.

Applicant's arguments have been considered but are not convincing. In the fiber optic sensor of Partin et al, cocaine or heroin molecules displace the fluorescently-labeled antigens on the antibodies immobilized to the optic fiber. For such a displacement interaction to occur at the antibodies, the fluorescently-labeled antigen must have an epitope (i.e. a reacting site) that is essentially identical to the epitope on

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the cocaine or heroin molecules being detected. Otherwise, the antibodies would not have binding affinity for both the fluorescently-labeled antigen and the cocaine or heroin molecules. With respect to a resonance material that is different from the structure of Partin et al, claim 6 only requires the resonance material be capable of generating a resonance phenomenon. The optic fiber (i.e. resonance material) in Partin et al supports totally internally reflected light which generates an evanescent field close to the surface of the optic fiber. The evanescent field is considered a resonance phenomenon.

6. Claims 6, 11, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Charles et al (WO 90/11525) for the reasons of record in the previous office action.

In response to this rejection, Applicants argue that claims 6 and 15 require a conjugated protein antigen with a reaction site which is essentially identical to that of the medical substance that is to be detected and which is fixed to the resonance material which is different from the structure of Charles et al. Applicants also argue that the instant invention uses a resonance phenomenon that is different from that of Charles et al.

Applicant's arguments have been considered but are not convincing. The sensor of Charles et al is for a displacement immunoassay. Analyte in a sample displace the analyte analogues on the antibodies immobilized on the surface of the sensor. Page 3 of Charles et al specifically states that the analyte analogues will be as near as possible or even completely identical to the analyte. Such a teaching suggests that the analyte analogues have reaction sites which are essentially identical to that of the analyte that is

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to be detected. Furthermore, if the analyte analogues did not have reaction sites (i.e. epitopes) that are essentially the same as those on the analyte, the antibodies could not have binding affinity for both the analyte and analyte analogues. With respect to a resonance material that is different from the structure of Charles et al, claims 6 and 15 only require the resonance material be capable of generating a resonance phenomenon (claim 6) and a resonance phenomenon resonating with an evanescent wave (claim 15). The sensor of Charles et al generates surface plasmon resonance on its surface which is considered a resonance phenomenon.

Contrary to Applicant's argument, the claims fail to recite any limitations that would suggest a different resonance phenomenon than what is exhibited in the sensor of Charles et al. Specifically, claim 15 requires a "resonance phenomenon resonating with an evanescent wave". It is well known that the production of a surface plasmon resonance signal at the surface of the metallic layer in the sensor of Charles et al initially requires the production of an evanescent field at the surface of the transparent support directly underneath the metallic film, i.e. a resonance phenomenon resonating with an evanescent wave.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6, 7, 9, 11-13, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batchelder et al (US Patent 4,844,613) in view of Charles et al (WO 90/11525) for the reasons of record in the previous office action.

In response to this rejection, Applicants argue that it is not clear as to how a specific arrangement in Batchelder et al renders obvious the present invention in claims 6-13 and 15-16.

Applicant's argument has been considered but is not convincing. Since Applicant's argument is solely directed to the Batchelder et al reference, Applicant's argument is considered not on point for a 103 obviousness rejection. The arrangement referred to in Batchelder et al by Applicants – wherein a change in antibody layer thickness causes a change of 0.01 degrees in the resonance angle for a source wavelength of 820 nm – is an indication of the level of sensitivity that can be achieved with the sensor of Batchelder et al. Thus, it is not clear as what point Applicant is arguing.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the



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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher L. Chin  
Primary Examiner  
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3/6/05